Author’s response to reviews

Title: Scheduling medicines as controlled substances: Addressing normative and democratic gaps through human rights-based analysis

Authors:

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Author’s response to reviews:

We are grateful to the reviewers for their useful comments and suggestions. Please find below a list of comments and how we have responded to them:

Reviewer 1

Comment: Could examples of how the schedules impact on the availability, accessibility and regulatory environment be made earlier in the piece (around top page 4). Some of this text appears later, but it would be preferable to clearly state the "on the ground" implications of a medicine/illicit drug being scheduled under the Conventions. A short description of the four schedules and the kinds of restrictions would also aid an unfamiliar reader.

Response: We have made relevant revisions. This comment is related to reviewer 2’s second recommendation. Both addressed in same section which now reads:

Central to the system are lists of substances set out in various ‘schedules’ according to their risk profile (Article 2, Single Convention, Article 2 1971 Convention. See Hallam et al 201448). Under the Single Convention there are four schedules, with schedules I and IV being the most restrictive. Substances on schedule I may also be placed on schedule IV if they are particularly risky and do not have significant medical value. Under the 1971 Convention, schedule I is the most restrictive. Once placed on these schedules, specific treaty obligations and domestic regulatory provisions apply, with important effects in terms of prescription, import and export controls. For example, in some countries domestic regulations impose highly burdensome procedures for procurement or stocking of scheduled medicines or arbitrarily restrict prescribing and dispensing of these medicines. Article 21 of the Single Convention imposes specific limitations on quantities that may be manufactured and imported. If placed on schedule I of the Single or 1971 Conventions, all of the controls in those conventions apply.

Comment: Page 7 line 5-6 "requires treaty amendment to repair", may be better expressed as "requires treaty amendment in order to be repaired".

Response: Sentence has been changed

Comment: "they also hinder the provision of sufficient justifications.." (page 3) is a difficult sentence.

Response: Sentence has been changed to make it easier to understand.
Comment: the long list of references are distracting (page 4, for example). I can see that INCB annual reports, UNODC WDR annual reports and WHO determinations are all relevant, but it could be better crafted regarding the references. For example the WHO reports for each drug could appear in turn after each drug is mentioned; the INCB reports could come directly after mention of the INCB (bottom page 4). For example "Annual reports of the International Narcotics Control Board (19-25) and the annual UNODC WDR (27-29) etc..

Response: This has been cleaned up.

Comment: Page 12, lines 47-49 it would be helpful to insert a reference supporting the claim that "large body of research on the negative effects in terms of availability and accessibility afterwards"

Response: Relevant references have been added to justify this claim.

Reviewer 2

Comment: Readers unfamiliar with the international drug control system may benefit from some clarification of the processes, actors and mandates at work during the scheduling process. For instance, further explanation of the roles of the WHO as well as the INCB and UNODC might make things clearer, or at least the placement of their introduction within the text may be reconsidered.

Response:

Amended the intro to address this by including v brief descriptions of what each body does/is. Also added a line on the technical and political aspects of scheduling in the introduction.

Comment:

In order to enhance clarity concerning necessary majorities between the conventions, the authors may consider starting a new paragraph after the word contain (p. 3 line 16).

Response:

Done

Comment:

Mindful of increasing discussion, within both academic literature and the 'policy community', about human rights and system-wide coherence, the authors may also consider adding a sentence or two on how the proposed re-framing of the scheduling process fits, and indeed reinforces, a broader re-conceptualization of the issue area taking place in some quarters

Response:

We have added a line about human rights mainstreaming and system wide coherence in the SDG era to the conclusion, with two new references (to UNGASS outcome resolutions, and UN Chief Exec Board for co-ordinations ‘common position’).